

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

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IN RE MEDTRONIC, INC.  
IMPLANTABLE DEFIBRILLATORS  
PRODUCTS LIABILITY LITIGATION

MDL NO. 05-1726 (JMR/AJB)

**REPORT AND RECOMMENDATION**

This documents relates to:  
All Cases

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In December 2005, the Judicial Panel on Multidistrict Litigation (“MDL”) consolidated hundreds of cases alleging various claims related to the sale of implantable Medtronic medical devices into an MDL action which was assigned to this Court.

In early 2006, the Court appointed Dan Gustafson and Charles Zimmerman as Co-lead counsel, as well as an eleven-member Plaintiffs’ Steering Committee (“PSC”) to assist Co-lead counsel in managing this MDL. *See* Order (January 24, 2006) [Docket No. 24].

Due to the significance of federal preemption issues, the Court ordered the filing of a master consolidated complaint for both individual and third-party payor cases, adopted an expedited discovery schedule, and set an early briefing schedule for Defendant Medtronic motions to dismiss and for summary judgment on preemption.

In light of the compressed timetable, the parties promptly negotiated agreements or put before the Court for resolution issues related to: a confidentiality order, document retention and production, a preservation order, deposition scheduling, bellwether trial selection, and associated scheduling. With the assistance of the Court during monthly status conferences, the parties moved through the myriad of case management challenges, kept the litigation progressing forward, and effectively managed the accelerated preemption discovery schedule.

The parties produced and reviewed hundreds of thousands of documents to prepare for depositions and dispositive motion practice. Key depositions were taken and the parties integrated this discovery into their briefing on Medtronic's summary judgment motion on preemption. The parties also worked to retain the necessary experts to opine on the issues relevant to these dispositive motions. After several months of accelerated and intensely contested discovery, and subsequent briefing, the Court denied Medtronic's preemption motion and permitted the case to proceed. *See* Order denying Medtronic's Motion for Summary Judgment (November 28, 2006) [Docket No. 287].

During the accelerated discovery on federal preemption, the PSC also filed briefs in opposition to Medtronic's Motions to Dismiss under Fed. R.

Civ. P. 12(b)(6). These motions raised various arguments related to the individual claims, the third-party payor claims, and the Medicare Secondary Payor Act claims implicating a variety of legal issues and applicable law. After substantial briefing, the parties prepared for and presented argument on these motions to the Court. The Court denied the motions to dismiss the individual and third-party payor complaints in their entirety. The Medicare Secondary Payor Act claims were dismissed.

The parties thereafter commenced preparation for bellwether trials<sup>1</sup> and worked towards completion of merits discovery and expert reports on the common issues. This process, again accelerated by the Court, resulted in the production of hundreds of Plaintiff's and Defendant's Fact Sheets containing information relating to the individual Plaintiffs. The parties then processed that information and began the bellwether trial selection process. Ultimately, the parties selected the bellwether trial cases after a long, difficult selection process. During this same time period, the parties produced and reviewed additional documents, prepared to take additional merits depositions, and prepared multiple expert disclosures pursuant to the Court's scheduling orders.

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<sup>1</sup> A bellwether trial is a trial involving a plaintiff and claims that are representative of a significant number of other cases. It is anticipated that a bellwether trial will yield results which will assist the parties in subsequent efforts to resolve other cases of a similar nature without the necessity of a trial.

After months of contentious discovery, extensive motion practice, key rulings on motions to dismiss and for summary judgment on preemption, and the selection of cases for the bellwether trials, the parties began Court-ordered mediation. Throughout the ensuing settlement discussions, the parties focused on reaching agreement on a private, confidential settlement model that included only those claimants who had filed cases or retained counsel. After multiple Court-supervised sessions and private negotiations, the parties reached a tentative framework for a conditional agreement.

As a result of these difficult and protracted negotiations, and with the assistance of the Court, the parties executed a Master Settlement Agreement (“MSA”) on June 4, 2007. Under the terms of the MSA, Medtronic agreed to pay \$93,750,000, which included a fund for eligible participating claimants (\$75,000,000) and a separate fund subject to approval by the Court for common benefit attorneys’ fees (\$18,750,000).

In conjunction with the MSA, the parties negotiated a confidentiality agreement which allowed the PSC to disclose the settlement terms for the limited purpose of obtaining the participation of the thousands of potential claimants in the MDL. The potential claimants enthusiastically endorsed the proposed settlement, which resulted in a significant over-subscription of eligible claimants. Consequently, the parties returned to the bargaining table

to revisit the previous settlement and proceed with further negotiations in an attempt to secure additional funding and resolve a broader universe of claims.

Upon resumption of negotiations, again with the assistance of the Court, the parties executed an Amended Master Settlement Agreement (“AMSA”) on September 14, 2007. The AMSA reaffirmed the basic agreement of the MSA, provided for additional funding to address the over-subscription problem, and provided for a separate renegotiation of the common benefit attorneys’ fees (not to exceed \$18,750,000) subsequent to the execution of the AMSA. Several additional negotiating sessions produced a separate agreement to pay common benefit attorneys’ fees in the amount of \$18,250,000.

In December 2007, the PSC proposed, and the Court adopted, an Allocation and Resolution Plan based on the recommendation from the PSC’s informally designated Allocation Committee. *See Order for Approval of Allocation and Resolution Process, In re Medtronic, Inc. Implantable Defibrillators Products Liability Litig.*, MDL No. 05-1726 (JMR/AJB)(D. Minn., January 14, 2008) [Docket No. 731]. The Court approved an Allocation and Resolution Plan in its January 14, 2007 Order, and that plan was thereafter implemented by the PSC.

The purpose of the Allocation and Resolution Plan was to establish a system, subject to the jurisdiction of this MDL Court,<sup>2</sup> whereby the claims of the Participating Claimants would be quickly, consistently, and fairly reviewed and resolved by the MDL Court. The Program was in lieu of any further litigation by the Participating Claimants with respect to their acquisition or use of a Recalled Device.

The Allocation and Resolution Plan has three components: (a) Individual Awards; (b) Enhanced Awards; and (c) a Subrogation Process. Only those Participating Claimants who were eligible for an Individual Award were eligible to submit claims to the Enhanced Award Fund. Eligibility for payment under the MDL Program was based on the Recommendation Form that Claimants submitted to the PSC and completion of a Claim Form (collectively referred to herein as “Claim Materials”), together with submission of medical records and other documentation required to support the Claimant’s claim.

a. Individual Awards

Participation in the settlement and eligibility for an award from the Individual Award Fund was based on objective criteria set forth in the Claim Materials and accompanying medical records. Factors considered in

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<sup>2</sup> The expansive power of a transferee court to conduct and enforce pretrial settlements is clear. *See In Re Joan Patenaude*, 210 F.3d 135, 144 (3d Cir. 2000); *In Re Managed Care Litig.*, 246 F.Supp.2d 1363, 1365 (J.P.M.L. 2003).

determining the eligibility and Individual Award amount included: (1) the implant of one or more Recalled Device(s); (2) the explant of one or more Recalled Device(s); (3) the duration of time between the implant and explant of the Recalled Device(s); and (4) the duration of time between the applicable Recall (i.e. the April 2004 or February 2005 Field Actions as set forth in the Scope Report) and the explant(s). Individual Awards were grouped into two categories: Category I (non-explant claims) and Category II (explant claims).

An Individual Award Fund was established to finance the Individual Awards for eligible and Participating Claimants. The proposed Individual Award Fund, as well as base Individual Award amounts, by Category, was set forth in the Summary Sheet which was attached as Exhibit B to the Court's January 14, 2008, Order adopting the Allocation Plan.

b. Enhanced Awards

Participating Claimants who have suffered documented emotional distress, additional and/or extensive hospitalizations, physical and health complications, extensive un-reimbursed economic injury, or other catastrophic injury or death causally related to the Recall and/or explant of a Recalled Device could seek additional compensation through an Enhanced Award Fund ("EIF"). Participating Claimants could apply, and may have

been eligible, for additional compensation through the Enhanced Award Fund if: (1) they satisfy the criteria for participation in the Individual Award Fund; and (2) they have a documented catastrophic or enhanced injury related to the Recall or explant of a Recalled Device. The amount for the proposed Enhanced Award Fund is set forth in the Summary Sheet which was attached as Exhibit B to the Court's January 14, 2008, Order adopting the Allocation Plan.

c. Subrogation Process - Medicare

The PSC retained The Garretson Law Firm ("TGLF") to verify the claims of Participating Claimants who may have potential Medicare obligations related to their Recalled Device and to facilitate reimbursement and resolution of Medicare's interests in the recoveries of Medicare-entitled participating Claimants. The amount set aside for the Medicare Fund is set forth in the Summary Sheet which was attached as Exhibit B to the Court's January 14, 2008, Order adopting this Plan.

d. Subrogation Process – Medicaid

To streamline the resolution of any individual Medicaid liens for Participating Claimants, TGLF will utilize a Medicaid-specific "Reimbursement Model" to determine the likely course of treatment associated with each compensable injury category. For those Participating



Claimants verified as Medicaid beneficiaries, TGLF will secure claims histories from the appropriate agency and audit each claim history against the Reimbursement Model checklist and will then resolve such liens individually. The final lien amount will be deducted from each respective Medicaid-entitled Participating Claimant's final award. The Garretson Law Firm will coordinate direct reimbursement to each Medicaid agency to ensure the satisfaction of the agencies' potential lien interest.

e. Subrogation Process – Private Third Party Payor Liens

Each Participating Claimant and his or her individual counsel are required to identify and determine whether or not any non-participating private third party payor subrogation interest exists and, to the extent such subrogation interest exists, whether those issues have been resolved. Prior to the release of Participating Claimants' total award amount, the Participating Claimant and his or her individual counsel must: (1) certify to the Special Master that subrogation liens have been satisfied; or (2) certify to the Special Master that TGLF has been engaged to resolve the outstanding subrogation liens; or (3) certify to the Special Master that the Participating Claimant's counsel has reviewed the contents of the Participating Claimant's file, conferred with Participating Claimant, and confirmed that no Notice of Lien or subrogation lien exists.

Each Participating Claimant has submitted a Claim Form and supporting documentation to the Co-Lead Counsel. On the Claim Form, the Participating Claimant indicated whether or not the Participating Claimant would seek an EIF award. Co-Lead counsel appointed a small group of lawyers to review each Claim Form and supporting documentation to verify the information on the Claim Form. These attorneys then followed up with individual plaintiffs' counsel regarding any inconsistencies or missing information.

The Claim Review Committee, appointed by the Court, then met to review the Non-EIF and EIF Claim Forms and make recommended allocations. The Claims Review Committee reviewed the Claim Forms and supporting documentation and provided the Special Master with an award recommendation for each Participating Claimant.

Each Participating Claimant was notified of the recommendation and was given the opportunity to file an objection to the recommended award with the Special Master, Magistrate Judge Arthur J. Boylan. The Claims Review Committee met and reviewed each objection and any supporting documentation submitted with the objection. The Claims Review Committee thereafter filed a response to the objection. After reviewing certain objections, the Claims Review Committee amended their

recommendation. In other cases, the Claims Review Committee renewed the original recommendation. The Participating Claimants were given the opportunity to file a reply with the Court. Several Participating Claimants accepted the Claims Review Committee's amended recommendation and so indicated to Co-Lead Counsel. In addition, each objecting claimant was advised that a hearing before the Special Master would be granted on request. Five claimants requested such hearing and counsel for each of them subsequently had an *ex parte* hearing by telephone conference with the Special Master.

The Special Master then reviewed each of the recommended allocations and each of the Objections filed by Participating Claimants, along with the Claims Review Committee's Response and the Reply.

In total, there are 2656 qualifying Participants in the settlement. Of those Participants, there were 831 explant claims and 1,825 non-explant claims. There were 638 Participating Claimants that sought an EIF award. The Claims Review Committee recommended an EIF award in 299 of those cases. 79 Participating Claimants appealed the recommended EIF award and 17 appealed the non-EIF recommendations. Those Participating Claimants who did not object to the Claims Review Committee's award recommendation are individually listed by claim number on an attachment to

this Report and Recommendation (“Attachment A”), along with the amount of the individual’s base award, the enhanced injury award, and the total award. The claims of the 86 persons objecting to the Claims Review Committee’s recommendation, including those who subsequently withdrew objections, are presented to the District Court by contemporaneously issued separate and individual Reports and Recommendations (under seal), each of which incorporates this comprehensive Report and Recommendation by reference. In addition, the Special Master has reviewed the claims and submissions of 27 arbitrarily selected non-objecting claimants as an exercise of his supervisory responsibilities and to insure substantial overall consistency in making award recommendations with respect to the claims of those individuals who submitted objections to Claims Review Committee awards.

Now therefore, the undersigned Special Master makes the following Report and Recommendation for the allocation of the Settlement Sums in this litigation:

### **RECOMMENDATION**

The Court **Hereby Recommends** that each claimant set forth on the attached chart, Attachment A, receive the base allocation and EIF award as indicated on that chart. This recommendation is based on the

recommendations of the Claims Review Committee and the Claim Forms submitted. These recommendations are also based on the Summary Term Sheet attached as Exhibit B to this Court's January 14, 2008 Order and the criteria set forth in that Term Sheet.

Dated \_\_June 3, 2008\_\_

\_\_\_\_s/Arthur J. Boylan\_\_\_\_\_  
Arthur J. Boylan  
United States Magistrate Judge  
Special Master